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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,320	06/02/2005	Akihiro Tada	TOYA107.007APC	3197

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EXAMINER
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SZNAIDMAN, MARCOS L

ART UNIT	PAPER NUMBER
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1612

NOTIFICATION DATE	DELIVERY MODE
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07/20/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
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<b>Office Action Summary</b>	<b>Application No.</b> 10/537,320	<b>Applicant(s)</b> TADA ET AL.	
	<b>Examiner</b> MARCOS SZNAIDMAN	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 7,9,12 and 13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7,9,12 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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Brandon,

Shouldn't "an individual in need thereof" be a WD rejection? Who are the individuals that are in need of inhibition of elongation of melanocytic dendrites?

That is a tough question, because it is unclear what patient populations are in need thereof. I probably would not, but would make a 112 2<sup>nd</sup> paragraph and tell them how you are interpreting the claims. E.g., what you are interpreting the patient population to be. For example, if the disease taught by the reference is associated with this elongation, well than you are interpreting a patient in need there to be one that has this disease.

DONE, see below

I may also object to the specification. It appears to be sometype of literal translation of the iapenese PCT. however, it is terrible English.

Done, see below

## DETAILED ACTION

This is office action is in response to applicant's request for continued examination filed on May 11, 2009.

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 22, 2009, including declarations under 37 CFR 1.132, has been entered.

***Status of Claims***

Cancellation of claim 8 and amendment of claims 7, 9 and 12 was already acknowledged in the previous Advisory Action mailed on May 4, 2009.

Claims 7, 9, and 12-13 are currently pending and are the subject of this office action.

Claims 7, 9 and 12-13 are presently under examination.

***Priority***

The present application is a 371 of PCT/JP03/15267 filed on 11/28/2003, and claims priority to foreign application JAPAN 2002-350733 filed on 12/03/2002.

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a certified English translation of the foreign application must be submitted in reply to this action. 37 CFR 41.154(b) and 41.202(e).

Failure to provide a certified translation may result in no benefit being accorded for the non-English application.

***Rejections and/or Objections and Response to Arguments***

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated (Maintained Rejections and/or Objections) or newly applied (New Rejections and/or Objections, Necessitated by Amendment or New Rejections and/or Objections not Necessitated by Amendment). They constitute the complete set presently being applied to the instant application.

***Specification Objection***

A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter.

***Claim Rejections - 35 USC § 112 (New Rejection not Necessitated by Amendment)***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 7, 9 and 12-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 7, 9 and 12-13 recite the phrase “individuals in need thereof”. It is not clear who are the individual that are in need of inhibition of elongation of melanocytic dendrites or what “disease”/“condition” elongation of melanocytic dendrites is associated with. For the current prosecution those individuals are interpreted as individuals with any skin disease.

***Claim Rejections - 35 USC § 102 (new Rejection Necessitated by Amendment)***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7, and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Remberg et. al. (WO 02/41909, cited by Applicant).

(Note: Due to the indefiniteness set forth above, inhibiting elongation of melanocytic dendrites has been interpreted as treating a skin disease. Or something like that)

Claim 7 recites a method for inhibiting elongation of melanocytic dendrites comprising: a step of applying Centaureidin and/or salt thereof to the skin of an individual in need thereof, whereby elongation of melanocytic dendrites is inhibited.

For claim 7, Remberg teaches a method of treating certain skin diseases like urticaria by applying to the skin a composition comprising Centaureidin (see abstract, page 1, first paragraph and page 3, see flavonol compositions).

The phrase: “for inhibiting elongation of melanocytic dendrites” is considered an inherent property of the method of Remberg (applying Centaureidin to the skin) as evidenced by Applicant’s own admission that contacting the skin with Centaureidin inhibits the elongation of melanocytic dendrites (see specification page 4). In other words, by practicing the method of Remberg: “contacting the skin with Centaureidin”, one would be practicing the invention of claim 7: “a method for inhibiting elongation of melanocytic dendrites comprising: a step of applying Centaureidin and/or salt thereof to the skin of an individual in need thereof, whereby elongation of melanocytic dendrites is inhibited”.

Also, “inhibiting elongation of melanocytic dendrites” is considered a mechanism of action. The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. *In re Wiseman*, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. *In re Baxter Travenol Labs*, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

Similarly, the phrase: “whereby elongation of melanocytic dendrites is inhibited” is not given any patentable weight because: the whereby clause represents the intended result of the process steps positively recited... See MPEP 2111.04: In *Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1329, 74 USPQ2d 1481, 1483 (Fed. Cir. 2005), the court held that when a “whereby” clause states a condition that is material to

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patentability; it cannot be ignored in order to change the substance of the invention.” *Id.* However, the court noted (quoting *Minton v. Nat ’l Ass ’n of Securities Dealers, Inc.*, 336 F.3d 1373, 1381, 67 USPQ2d 1614, 1620 (Fed. Cir. 2003)) that a “whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited.” *Id.* In the present case, Remberg teaches the same active steps of the instant application: applying Centaureidin to the skin.

Claim 12 recites a method for inhibiting elongation of melanocytic dendrites comprising applying a skin preparation for external use comprising 0.005% to 5% by weight of Centaureidin or a salt thereof, whereby elongation of melanocytic dendrites is inhibited. Claim 12 is similar to claim 7, except that recites:” a skin preparation for external use comprising 0.005 to 5% by weight of Centaureidin”.

For claim 12, Remberg further teaches a composition comprising 0.005% of Centaureidin (5 mg of Centaureidin in 100 g of dry plant material (see page 3) which anticipates the instant claimed range.

The statement in claim 1: “for external use” is considered an intended use and does not add any new limitation to the claim. *Catalina Mktg. Int’l, Inc. V. Coolsavings.com, Inc.*, 289 F.3d 801, 808, 62 USPQ2d 1781, 1785 (fed. Cir. 2002). “The recitation of a new intended use for an old product does not make a claim to that old product patentable.” *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997).



Claim 13 further limits claim 12, wherein the skin preparation for external use is a cosmetic. Remberg is silent regarding cosmetic preparations of centaureidin. However a composition for the treatment of urticaria which can be applied to the skin can reasonably interpreted as being a cosmetic.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Remberg et. al. (WO 02/41909, cited by Applicant) as evidenced by Applicant's own declarations.

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Claim 9 further limits claim 7, wherein the skin has dyschromatosis on which tyrosine inhibitors have insufficient effect.

Remberg teaches all the limitations of claim 7, except for the skin having dyschromatosis on which tyrosine kinase inhibitors have insufficient effect.

However, Dyschromatosis, as evidenced by the specification (see page 2, second paragraph), is a skin disease. Since Remberg teaches applying Centaureidin to the skin and since dyschromatosis is also a disease of the skin, at the time of the invention it would have been prima facie obvious to the skilled in the art to apply centaureidin to a skin with any disease including dyschromatosis on which tyrosine kinase inhibitors have insufficient effect.

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### ***Withdrawn Rejections and/or Objections***

#### ***Claims rejected under 35 USC 103 (a)***

Due to Applicant's amendments of the claims and due to Applicant's arguments and data presented in the declaration under 37 CFR 1.132 filed on May 4, 2009 the 103(a) rejection is now moot.

Rejection under 35 USC 103(a) is withdrawn.

However, upon new evidence and prior art a new 102 (b) and 103 (a) rejection was applied (see above).

***Conclusion***

No claims are allowed.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARCOS SZNAIDMAN/  
Examiner, Art Unit 1612  
June 30, 2009

/Brandon J Fetterolf/

Primary Examiner, Art Unit 1642